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Intarcia Ref. No. INT 004.10 / USSN 10/004,118 PATENT

#### CERTIFICATE OF FIRST CLASS MAILING

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Gary R. Fabian

Printed Name

Guy V From

IF July 2007

Signature

Date of Deposit

IN THE UNITED STATES PATI	ENT AND TRADEMARK OFFICE
In Re Application of: Stanford Mark Moran	Confirmation No. 8022
Serial No.: 10/004,118	Art Unit: 1647
Filing Date: 30 October 2001	Examiner: Seharaseyon, J.
Title: METHOD FOR TREATING DISEASES	WITH OMEGA INTERFERON

#### **TRANSMITTAL**

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Transmitted herewith for filing in the above-referenced application are the following documents:

- 1. Transmittal;
- 2. Modified Form 1449 and copies of 27 non-US Patent publications;
- 3. Supplemental Information Disclosure Statement Under 37 C.F.R. § 1.97;
- 4. Certificates of First Class Mailing; and
- 5. Return Receipt Postcard.

#### Authorization to Charge Deposit Account.

No additional fees are believed due in connection with this paper. However, the Commissioner is hereby authorized to charge to Deposit Account No. 504212 (please reference INT 004.10) any fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 which may be required by this paper, with the exception of the payment of the Issue Fee.

Respectfully submitted,

Dated: 17 July 2007

Bv

Gary R. Fabian, Ph.D. Registration No. 33,875 Agent for Applicant

Intarcia Therapeutics, Inc. 2000 Powell Street Suite 1640 Emeryville, CA 94608 Commissioner for Patents

P.O. Box 1450 Alexandrapy 22313-1450

#### FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary) Sheet \_1\_ of \_6

Confirmation No.: 8022

In the Application of: Stanford Mark Moran

Serial No.: 10/004,118

Art Unit: 1647 Filed: 30 October 2001 Examiner: Seharaseyon, J.

Title: METHOD FOR TREATING DISEASES WITH OMEGA INTERFERON

		•	U.S. PATENT DOCUM	U.S. PATENT DOCUMENTS					
Exam. Init.	Ref. Desig.	Document No.	Name	Date	Class	Sub Class	Filing Date		
	A-01	4,211,771	Witkowski et al.	07/08/1980					
	A-02	4,695,623	Stabinsky	09/22/1987					
	A-03	4,727,138	Goeddel et at.	02/23/1988					
	A-04	4,762,791	Goeddel et al.	08/09/1988					
	A-05	4,820,638	Swetly et al.	04/11/1989					
	A-06	4,845,196	Cowling	07/04/1989					
	A-07	4,897,471	Stabinsky	01/30/1990					
	A-08	4,915,954	Ayer et al.	04/10/1990		-			
	A-09	4,917,895	Lee et al.	04/17/1990					
	A-10	4,929,554	Goeddel et al.	05/29/1990					
	A-11	4,976,966	Theeuwes et al.	12/11/1990			<u> </u>		
	A-12	5,004,689	Fiers et al.	04/02/1991					
	A-13	5,112,614	Magruder et al.	05/12/1992					
	A-14	5,120,832	Goeddel et al.	06/09/1992					
	A-15	5,221,278	Linkwitz et al.	06/22/1993					
	A-16	5,231,176	Goeddel et al.	07/27/1993					
	A-17	5,318,558	Linkwitz et al.	06/07/1994					

Examiner:	C	Date Considered:

# FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary) Sheet \_2\_ of \_6

In the Application of: Stanford Mark Moran

Serial No.: 10/004,118

Confirmation No.: 8022

Art Unit: 1647

Filed: 30 October 2001 Examiner: Seharaseyon, J.

Title: METHOD FOR TREATING DISEASES WITH OMEGA INTERFERON

U.S. PATENT DOCUMENTS							
Exam. Init.	Ref. Desig.	Document No.	Name	Date	Class	Sub Class	Filing Date
	A-18	5,324,280	Wong et al.	06/28/1994			
	A-19	5,368,863	Eckenhoff et al.	11/29/1994			
	A-20	5,413,572	Wong et al.	05/09/1995			
	A-21	5,443,459	Wong et al.	08/22/1995		<del>                                     </del>	
	A-22	5,529,914	Hubbell et al.	06/25/1996			
	A-23	5,543,156	Roorda et al.	08/06/1996			
	A-24	5,574,137	Gray et al.	11/12/1996			<u> </u>
	A-25	5,602,010	Hauptmann et al.	02/11/1997			
	A-26	5,660,847	Magruder et al.	08/26/1997			
	A-27	5,690,925	Gray et al.	11/25/1997	•		<u> </u>
	A-28	5,728,396	Peery et al.	03/17/1998			
	A-29	5,795,779	McCormick et al.	08/18/1998			
	A-30	5,807,876	Armistead et al.	09/15/1998			
	A-31	5,858,746	Hubbell et al.	01/12/1999			
	A-32	5,939,286	Johnson et al.	08/17/1999			
	A-33	5,985,305	Peery et al.	11/16/1999	·		
	A-34	6,113,938	Chen et al.	09/05/2000			1

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# FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary) Sheet 3 of 6

In the Application of: Stanford Mark Moran

Serial No.: 10/004,118

Confirmation No.: 8022

Art Unit: 1647

Filed: 30 October 2001

Examiner: Seharaseyon, J.

Title: METHOD FOR TREATING DISEASES WITH OMEGA INTERFERON

	U.S. PATENT DOCUMENTS						
Exam. Init.	Ref. Desig.	Document No.	Name	Date	Class	Sub Class	Filing Date
	A-35	6,129,761	Hubbell	10/10/2000			
	A-36	6,204,022	Johnson et al.	03/20/2001			,
	A-37	6,172,046	Albrecht	01/09/2001			

			FOREIGN PATENT DOC	UMENTS	,		
Exam. Init.	Ref. Desig.	Document No.	Publication Date	Country or Patent Office	Class	Sub Class	Translation YES NO
	B-01	WO 03/030923 A1	17-Apr-2003	WIPO/PCT			

	OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)					
Exam. Init.	Ref. Desig.	Description				
	C-01	ADAMSON et al., "Phase I trial and pharmacokinetic study of all-trans-retinoic acid administered on an intermittent schedule in combination with interferon-alpha2a in pediatric patients with refractory cancer" J Clin Oncol (1997) Nov; 15(11):3330-3337				
	C-02	BAILON et al., "Rational Design of a Potent, Long-lasting Form of Interferon: A 40 kDa Branched Polyethylene Glycol-conjugated Interferon Alpha-2a for the Treatment of Hepatitis C" Bioconjugate Chemistry (2001), 12(2):195-202				

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Examiner:	Date Considered.

# FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary) Sheet <u>4</u> of <u>6</u>

In the Application of: Stanford Mark Moran

Serial No.: 10/004,118 Filed: 30 October 2001 Confirmation No.: 8022

Art Unit: 1647

Examiner: Seharaseyon, J.

Title: METHOD FOR TREATING DISEASES WITH OMEGA INTERFERON

		R DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)
Exam. Init.	Ref. Desig.	Description
	C-03	DORR et al., "Phase I-II trial of interferon-alpha 2b by continuous subcutaneous infusion over 28 days" J Interferon Res (1988); 8:717-725
	C-04	FRANCHETTI et al., "Furanfurin and Thiophenfurin: Two Novel TiazofurinAnalogues. Synthesis, Structure, Antitumor Activity, and Interactions with Inosine Monophosphate Dehydrogenase" Journal of Medicinal Chemistry (1995); 38(19):3829-3837
	C-05	GAUSE et al., "Phase I study of subcutaneously administered interleukin-2 in combination with interferon alfa-2a in patients with advanced cancer" J Clin Oncol (1996) Aug; 14(8):2234-2241
	C-06	GOSLAND et al., "A phase I trial of 5-day continuous infusion cisplatin and interferon alpha" Cancer Chemother Pharmacol (1995); 37(I-2):39-46
	C-07	HEATHCOTE et al., "Peginterferon alfa-2a in Patients With Chronic Hepatitis C and Cirrhosis" New England Journal of Medicine (2000); 343(23):1673-1680
	C-08	HORTON et al., "Antitumor effects of interferon-omega: in vivo therapy of human tumor xenografts in nude mice" Cancer Res 59(16):4064-4068 (Aug. 1999)
	C-09	HUBEL et al., "A phase I/II study of idarubicin, dexamethasone and interferon-alpha (1-Dexa) in patients with relapsed or refractory multiple myeloma" Leukemia (1997) Dec; 11 Suppl 5:S47-S51
	C-10	IACOBELLI et al., "A phase I study of recombinant interferon-alpha administered as a seven-day continuous venous infusion at circadian-rhythm modulated rate in patients with cancer" Am J Clin Oncol (1995); 18(1):27-31
	C-11	ISHIWATA et al., "Clinical effects of the recombinant feline interferon-omega on experimental parvovirus infection in beagle dogs" (1998); J Vet Med Sci 60(8):911-917
	C-12	KIRKWOOD et al., "Interferon alfa-2b adjuvant therapy of high-risk resected cutaneous melanoma: The Eastern Cooperative Oncology Group Trial EST 1684" J Clin Oncol (1996) 14(1):7-17

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Examiner:	Date Considered:

Dkt No. INT 004.10

# FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary) Sheet <u>5</u> of <u>6</u>

In the Application of: Stanford Mark Moran

Serial No.: 10/004,118 Filed: 30 October 2001 Confirmation No.: 8022

Art Unit: 1647

Examiner: Seharaseyon, J.

Title: METHOD FOR TREATING DISEASES WITH OMEGA INTERFERON

	OTHE	R DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)
Exam. Init.	Ref. Desig.	Description
	C-13	MOTZER et al., "Phase I trial of 40-kd branched pegylated interferon alfa-2a for patients with advanced renal cell carcinoma" Journal of Clinical Oncology (2001); 19(5):1312-1319
	C-14	NEUMANN et al., "Hepatitis C Viral Dynamics In Vivo and the Antiviral Efficacy of Interferon-alpha Therapy" Science 282 (1998): 103-107.
	C-15	RAJKUMAR et al., "Phase I evaluation of radiation combined with recombinant interferon alpha-2a and BCNU for patients with high-grade glioma" Int J Radiat Oncol Biol Phys (1998) Jan 15; 40(2):297-302
	C-16	ROTH et al., "High Dose Etretinate and Interferon-alphaA Phase I Study in Squamous Cell Carcinomas and Transitional Cell Carcinomas" Acta Oncol (1999); 38(5):613-617
	C-17	SULKOWSKI et al., "Pegylated Interferon Alfa-2A (Pegasys™) and Ribavirin Combination Therapy for Chronic Hepatitis C: A Phase II Open-Label Study" Gastroenterology (2000); 118(4_Suppl_2), Abstract 236
	C-18	TALPAZ et al., "Phase 1 study of polyethylene glycol formulation of interferon alpha-2B (Schering 54031) in Philadelphia chromosome-positive chronic myelogenous leukemia" Blood (2001); 98(6):1708-1713
	C-19	TRUDEAU et al., "A phase I study of recombinant human interferon alpha-2b combined with 5-fluorouracil and cisplatin in patients with advanced cancer" Cancer Chemother Pharmacol (1995); 35(6):496-500
	C-20	VOKES et al., "A phase I trial of concomitant chemoradiotherapy with cisplatin dose intensification and granulocyte-colony stimulating factor support for advanced malignancies of the chest" Cancer Chemother Pharmacol (1995); 35(4):304-312
	C-21	ZEUZEM et al., "Peginterferon Alfa-2a in Patients with Chronic Hepatitis C" New England Journal of Medicine (2000), 343(23):1666-1672
	C-22	InterMune® Inc. Infergen® (Interferon alfacon-1). 2002
	C-23	Hoffmann-La Roche Inc. Pegasys® (peginterferon alfa-2a). 2002
	C-24	Roche Pharmaceuticals. ROFERON®-A (Interferon alfa-2a, recombinant). 2003
	C-25	Schering Corporation. Intron® A for Injection. 2001

Examiner: Da	ate Considered:

Dkt No. INT 004.10

# FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary) Sheet \_6\_ of \_6

In the Application of: Stanford Mark Moran

Serial No.: 10/004,118

Confirmation No.: 8022

Art Unit: 1647

Filed: 30 October 2001

Examiner: Seharaseyon, J.

Title: METHOD FOR TREATING DISEASES WITH OMEGA INTERFERON

OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)			
Exam. Init.	Ref. Desig.	Description	
	C-26	Schering Corporation. PEG-Intron™ (Peginterferon alfa-2b). Powder for Injection. 2003	

Examiner:	Date Considered:



CERTIFICATE OF FIRST CLASS MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service under 37 CFR §1.8 on the date indicated below and with sufficient postage addressed to Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450.

Gary R. Fabian

Printed Name

Guy R. Fabian

17 July 2007

Signature

Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE			
In Re Application of: Stanford Mark Moran	Confirmation No. 8022		
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### SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

The information listed below may be material to the examination of the above-identified application. A completed Form PTO-1449 and copies of the cited non-patent references accompany this paper.

Further, because this application was filed after 30 June 2003, copies of cited U.S. Patent and U.S. Patent Application publications have not been submitted pursuant to the waiver described in pre-OG Notice "Information Disclosure Statements may be filed without copies of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003.

Applicants would appreciate the Examiner's initialing and returning the form to indicate that the references have been reviewed and made of record in the present application.

This Information Disclosure Statement under 37 CFR § 1.97 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to

the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

#### **Authorization to Charge Deposit Account:**

The Commissioner is hereby authorized to charge No additional fees are believed due in connection with this paper. However, the Commissioner is hereby authorized to charge to Deposit Account No. **504212** (please reference docket number **INT 004.10**) any fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 which may be required by this paper, with the exception of the payment of the Issue Fee.

Respectfully submitted,

Date: 7 Lly 2007

By

Gary R. Fabian, Ph.D. Agent for Applicants Registration No. 33,875

Intarcia Therapeutics, Inc. 2000 Powell Street
Suite 1640
Emeryville, CA 94608